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ATTORNEY DOCKET NO. CONFIRMATION NO. APPLICATION NO. FILING DATE FIRST NAMED INVENTOR 10/774,247 Siegfried Noctzel 02/06/2004 RDID 03026 US 9104 (WP21397) 7590 09/19/2007 **EXAMINER** Brent A. Harris Roche Diagnostics Operations, Inc. WALLENHORST, MAUREEN 9115 Hague Road, Bldg. D **ART UNIT** PAPER NUMBER Indianapolis, IN 46250 1743 MAIL DATE **DELIVERY MODE** 09/19/2007 **PAPER**

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | Application No. | Applicant(s) | |
|--|--|--|----------|
| Office Action Summary | 10/774,247 | NOETZEL ET AL. | |
| | Examiner | Art Unit | |
| | Maureen M. Wallenhorst | 1743 | |
| The MAILING DATE of this communication app Period for Reply | ears on the cover sheet with | the correspondence addres | SS |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period was prepared to reply within the set or extended period for reply will, by statute any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICAGE 36(a). In no event, however, may a replaying and will expire SIX (6) MONTH, cause the application to become ABAN | ATION. y be timely filed IS from the mailing date of this community NDONED (35 U.S.C. § 133). | |
| Status | | • | |
| 1) Responsive to communication(s) filed on | | | |
| | – action is non-final. | | |
| 3) Since this application is in condition for allowar | | e prosecution as to the me | rite ie |
| closed in accordance with the practice under E | | - | 1110 10 |
| , | ex parto quayro, 1000 O.D. | 11, 400 0.0. 210. | |
| Disposition of Claims | | • | |
| 4) Claim(s) 1-24 is/are pending in the application. | | | |
| 4a) Of the above claim(s) is/are withdraw | wn from consideration. | · · | |
| 5) Claim(s) is/are allowed. | | | |
| 6) Claim(s) is/are rejected. | | | |
| 7) Claim(s) is/are objected to. | | | |
| 8) Claim(s) <u>1-24</u> are subject to restriction and/or 6 | election requirement. | | |
| Application Papers | | | |
| 9) The specification is objected to by the Examine | er. | | |
| 10) The drawing(s) filed on is/are: a) acc | | the Examiner. | |
| Applicant may not request that any objection to the | | | • |
| Replacement drawing sheet(s) including the correct | • | , . | .121(d). |
| 11) The oath or declaration is objected to by the Ex | • | | • • |
| Priority under 35 U.S.C. § 119 | | | |
| 12)⊠ Acknowledgment is made of a claim for foreign a)⊠ All b)□ Some * c)□ None of: | priority under 35 U.S.C. § 1 | 19(a)-(d) or (f). | |
| 1. Certified copies of the priority documents | s have been received. | | |
| 2. Certified copies of the priority document | • • | | |
| 3. Copies of the certified copies of the prior | • | eceived in this National Stag | ge |
| application from the International Bureau | | | |
| * See the attached detailed Office action for a list | of the certified copies not re | ceived. | |
| | • | | |
| Attachment(s) | | | |
| 1) Notice of References Cited (PTO-892) | 4) Interview Sur | nmary (PTO-413) | |
| 2) Dotice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/i | Mail Date | |
| 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date | | rmal Patent Application | |
| - apor recisional Date, | 6) | • | , |

Art Unit: 1743

DETAILED ACTION

Election/Restrictions

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-10 and 23-24, drawn to an analytical test element comprising a sample channel and a dilution channel, classified in class 436, subclass 179.
 - II. Claims 11-22, drawn to an analytical test element comprising a first channel for determining total hemoglobin and a second channel for determining glycohemoglobin, classified in class 436, subclass 66.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are not disclosed as capable of use together and they have different modes of operation and effects. The invention of Group I includes a dilution channel therein with a separation means for retaining corpuscular blood components, which the invention of Group II does not have. The invention of Group II includes channel structures for determining total hemoglobin and glycated hemoglobin, which the invention of Group I does not have. Therefore, the invention of Group I operates to dilute a blood sample without measuring total hemoglobin and glycated hemoglobin, while the invention of Group II operates to measure total hemoglobin and glycated hemoglobin without diluting a blood sample.

Application/Control Number: 10/774,247

Art Unit: 1743

- 3. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.
- 4. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Application/Control Number: 10/774,247

Art Unit: 1743

6.

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-

1266. The examiner can normally be reached on Monday-Thursday from 6:00 AM- 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the

organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would

like assistance from a USPTO Customer Service Representative or access to the automated

information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Maureen M. Wallenhorst Primary Examiner Page 4

Art Unit 1743

mmw

September 5, 2007

Maurien M. Wallenhorst MAUREEN M. WALLENHORST PRIMARY EXAMINER

GROUP 1999 1700